 K063427

Appendix A11 The 510(k) Summary

JUL 25 2007

Applicant & Submitter :	Lynton Lasers Limited
Address :	Lynton House, Manor Lane, Holmes Chapel, Cheshire, CW4 8AF, UK
Telephone :	+44 (0)1477 536977
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Contact Person :	Dr. Andrew J Berry AJBerry@lynton.co.uk
Preparation Date :	9th November 2006
Device Submitted :	LUMINA Intense Pulsed Light (& Laser) System
Common Name :	Light Therapy Device
Classification Name :	Laser surgical instrument for use in general and plastic surgery and in dermatology.
Product Code :	GEX
Predicate Device :	Lovely System (Lovely II, or "Harmony"), manufactured by MSq(M2) Ltd. 7 Haeshel St. P.O.B 3021 Caesarea Industrial Park, 38900 Israel (K033946, K042000)
Device Description :	The LUMINA Intense Pulsed Light (& Laser) System is a platform for a range of Intense Pulse Light (IPL) Handpieces and an internal Nd:YAG Laser Accessory for a number of applications in general and plastic surgery and dermatology, including : • Hair Removal • Vascular Lesion treatments • Pigmented Lesion treatments • Tattoo removal • Facial wrinkle reduction The System includes :

- A floor-standing main cabinet unit (including the central control electronics) that controls timing and dosing parameters. This unit also contains a water-cooling system used to remove heat from the IPL Handpieces and the internal Nd:YAG Laser Accessory (if fitted).
- A control and display panel including a touchscreen.
- A range of optional IPL handpieces that include the flashlamp light source, electrical and cooling water connections.

Intended Use :

The LUMINA Intense Pulsed Light (& Laser) System is intended for use in applications requiring the selective ablation, vaporization and photothermolysis (photocoagulation or coagulation) of soft tissue in the medical specialities of general & plastic surgery and dermatology.

Indications for Use :

The LUMINA Intense Pulsed Light (& Laser) System, when using the IPL Handpieces, is indicated for :

- The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation and ephelides (freckles).
- The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
- The removal of unwanted hair and to effect stable long-term or permanent hair removal.
- Indicated for use on all skin types (Fitzpatrick I-IV)

The LUMINA Intense Pulsed Light (& Laser) System, when using the internal Nd:YAG Laser Accessory at 1064nm (Long Pulsed and Q-Switched), is indicated for treatment and clearance of :

- Benign vascular lesions such as, but not limited to treatment of :
  > Port wine stains
  > Hemangiomas
  > Superficial and deep telangiectasias (venulectasias)
  > Reticular veins (0.1 - 4.0mm diameter) of the leg
  > Rosacea
  > Venus Lake
  > Leg veins
  > Spider veins
  > Poikiloderma of Civatte
  > Angiomas
- The removal of blue or black tattoos (significant reduction in the intensity of black and/or blue/black tattoos)
- The non-ablative treatment of facial wrinkles, such as, but not limited to:
  > Periocular wrinkles
  > Perioral wrinkles
- The removal of unwanted hair, for stable long-term or permanent hair reduction through selective targeting of melanin in hair follicles.
- Removal or lightening of unwanted hair (with and without adjuvant preparation).
- Pseudofolliculitis barbae (PFB)
- Indicated for use on all skin types (Fitzpatrick I-IV)

The LUMINA Intense Pulsed Light (& Laser) System, when using the internal Nd:YAG Laser Accessory at 532nm (Long Pulsed and Q-Switched), is indicated for :

- Tattoo removal :
  > Light blue
  > Yellow
  > Red
- Benign pigmented lesions such as, but not limited to :
  > Café au lait macules
  > Lentigines (senile and solar)
  > Freckles (ephelides)

> Chloasma
> Nevi
> Nevus spillus
> Nevus of Ota
> Becker's nevi

Performance Data : The LUMINA Intense Pulsed Light (& Laser) System complies with the European Medical Devices Directive 93/42/EEC (Annex II) and the standards IEC 60601-1, IEC 60601-1-2, IEC 60601-2-22 and IEC 60825-1

Substantial Equivalence : The LUMINA Intense Pulsed Light (& Laser) System is substantially equivalent in terms of technological characteristics, performance, intended use, indications for use and operator interface to the previously cleared Lovely System (Lovely II, or "Harmony" System), cleared under K033946, K042000. There are no unique applications, indications, materials or specifications presented. Evidence of equivalence has been demonstrated through :

- The LUMINA Intense Pulsed Light (& Laser) System's intended use and indications for use were previously cleared by the FDA for the predicate device.
- The technical characteristics of The LUMINA Intense Pulsed Light (& Laser) System are similar to those of the predicate device.
- Laser output values of the LUMINA Intense Pulsed Light (& Laser) System are similar to those of the predicate device (and other FDA cleared devices on the market)
- The predicate device, and other previously cleared devices with similar output specifications, have a proven safety and effectiveness in the treatment of the claimed indications.
- Safety and performance testing.

Therefore, the LUMINA Intense Pulsed Light (& Laser) System is substantially equivalent to the predicate device cited above and raises no new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2007

Lynton Lasers Ltd.
% Dr. Andrew J. Berry
Technical Director
Lynton House, Manor Lane
Holmes Chapel, Cheshire CW4 8AF
United Kingdom

Re: K063427
Trade/Device Name: LUMINA Intense Pulsed Light (& Laser) System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: June 21, 2007
Received: June 25, 2007

Dear Dr. Berry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

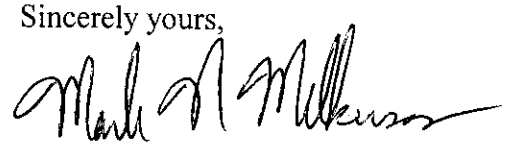
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) : K063427

Device Name : LUMINA Intense Pulsed Light (& Laser) System

Indications for Use :

The LUMINA Intense Pulsed Light (& Laser) System is intended for use in applications requiring the selective ablation, vaporization and photothermolysis (photocoagulation or coagulation) of soft tissue in the medical specialities of general & plastic surgery and dermatology, as follows :

The LUMINA Intense Pulsed Light (& Laser) System, when using the IPL Handpieces, is indicated for :

- The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation and ephelides (freckles).
- The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
- The removal of unwanted hair and to effect stable long-term or permanent hair removal.
- Indicated for use on all skin types (Fitzpatrick I-IV)

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K064327

510(k) Number (if known) : K063427

Device Name : LUMINA Intense Pulsed Light (& Laser) System

Indications for Use : - Continued from previous page -

The LUMINA Intense Pulsed Light (& Laser) System, when using the internal Nd:YAG Laser Accessory at 1064nm (Long Pulsed and Q-Switched), is indicated for treatment and clearance of :

- Benign vascular lesions such as, but not limited to treatment of :
  > Port wine stains
  > Hemangiomas
  > Superficial and deep telangiectasias (venulectasias)
  > Reticular veins (0.1 - 4.0mm diameter) of the leg
  > Rosacea
  > Venus Lake
  > Leg veins
  > Spider veins
  > Poikiloderma of Civatte
  > Angiomas
- The removal of blue or black tattoos (significant reduction in the intensity of black and/or blue/black tattoos)

Prescription Use √ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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510(k) Number (if known) : K063427

Device Name : LUMINA Intense Pulsed Light (& Laser) System

Indications for Use : - Continued from previous page -

The LUMINA Intense Pulsed Light (& Laser) System, when using the internal Nd:YAG Laser Accessory at 1064nm (Long Pulsed and Q-Switched), is indicated for treatment and clearance of – continued - :

- The non-ablative treatment of facial wrinkles, such as, but not limited to:
  > Periocular wrinkles
  > Perioral wrinkles
- The removal of unwanted hair, for stable long-term or permanent hair reduction through selective targeting of melanin in hair follicles.
- Removal or lightening of unwanted hair (with and without adjuvant preparation).
- Pseudofolliculitis barbae (PFB)
- Indicated for use on all skin types (Fitzpatrick I-IV)

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Device Name : LUMINA Intense Pulsed Light (& Laser) System

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- Tattoo removal :
  > Light blue
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- Benign pigmented lesions such as, but not limited to :
  > Café au lait macules
  > Lentigines (senile and solar)
  > Freckles (ephelides)
  > Chloasma
  > Nevi
  > Nevus spillus
  > Nevus of Ota
  > Becker's nevi

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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